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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,495	12/30/2003	Charles R. Roe	10347/20019	8734

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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,495	ROE, CHARLES R.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,19-47 and 49-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,19-47 and 49-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 17,19-47 and 49-57 are pending.

The response filed **6/6/07** presents remarks and arguments to the office action mailed **12/ 6/06**. Applicants' request for reconsideration of the rejection of claims in the last office action is acknowledged.

Applicants' arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Objections

Claims 23-26, 30, 34, 38 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be in the alternative form. See MPEP § 608.01(n).

Claims 23-26, 30, 34, 38 depend from a cancelled claim. Claim 18 is cancelled.

Claim Rejections - 35 USC § 112

Claims 42-47 and 49-52 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues (with regard to undue experimentation of the use of the broad term seven-carbon fatty acid) that if any experimentation would be necessary such experimentation would clearly not be undue, and that the specification provides more support to enable the skilled artisan to make and use the present invention.

The interpretation of the claim is to give it its broadest meaning. While the application or claims are enabled for a few seven-carbon fatty acids such as those listed in the specification § 0074, this showing clearly does not provide enablement for every seven-carbon fatty acid that may be present in a composition, as claimed, and will present both undue experimentation and an undue burden to the skilled artisan to determine which compositions comprising a seven-carbon acid will be suitable to treat cardiac disorders, such as cardiac muscle weakness. The state of the prior art is such that it involves *in vitro* and *in vivo* screening to determine which compositions exhibit the desired pharmacological activities. It is noted that thepharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher,* 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is***, the more specific enablement is necessary in order to satisfy the statute***. Further, the mode of action ofcardiovascular drugs is often unknown or very unpredictable and administration of them may be accompanied by undesirable side effects.

Applicant's limited working example does not provide enablement to one of ordinary skill in the cardiology art to use the numerous compositions comprising a seven-carbon chain acid as encompassed by instant claims 17, 42, 47 and 53.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-33, 37, 41-47 and 55-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to instant claim 25, the claim recites ".... of the even carbon fatty acid metabolic pathway". It is unclear what is intended as n-heptanoic acid is not an even carbon chain, but rather odd. Clarification is requested. Claims dependent on 25 are included in the limitation, ie., claims 29, 33, 37 and 41.

Claim 25 recites the limitation "fatty"; however, in claim 17 there is no provision for "fatty". There is insufficient antecedent basis for this limitation in the claim.

Further, a "substituted" n-heptanoic acid in claim 21 lacks proper antecedent basis in independent claim 17.

Claims 26-32 lack clarity. These claims recite one or more doses. What is considered to be the upper limit of more doses? Is it two, fifty or indefinite? Clarification is requested.

With regard to claims 42-46, the term "from about", is not defined by the claim; the specification does not provide a standard for ascertaining the requisite degree; one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The claims lack clarity as to whether "from" (a lower limit) or "about"(broadening

limitation, both higher and lower) controls the metes and bounds of the phrase "from about".

Claim 47 recites the term "directly". The term is vague and indefinite because it is unclear to what "directly" refers.

Claims 55-57 recite the term "between about" which is not defined by the claim; the specification does not provide a standard for ascertaining the requisite degree; one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, because one of skill will not be able to determine which term is in control. The claims lack clarity as to whether "between" (Intermediate to, as in quantity, amount, or degree) or "about"(broadening limitation, both higher and lower) controls the metes and bounds of the phrase "between about".

In claim 21 those substituents of n-heptanoic acid contemplated are unknown which reders this claim indefinite.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 17,19-47 and 49-57 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 25-27, 37-40, 42-45 and 47-56 of U.S. Patent No. 10/371,385. Although the conflicting claims are not identical, they are not patentably distinct from each other. The reasons are as follows:

The copending application teaches an infant formula for increasing growth rate comprising seven carbon fatty acids such as n-heptanoic acid and a triglyceride comprising n-heptanoic acid (n-heptanoin). The present application teaches methods of treating a patient with a cardiac disorder comprising administering the instant composition of the copending application. The method claims of the present application are an obvious variation of the claims of the copending application.

Both applications recite using the same compositions and/or derivatives thereof. See current application claims 17,19-47 and 49-57 and copending application claims 25-27, 38-40, 42-45 and 47-56. As evident by Salzer et al., infants with congenital heart disease have poor weight and length gain (see introduction) and, therefore, need a nutritional supplement. The claimed compositions would have been obvious to one of ordinary skill in the art to use in the treatment of infants with congenital heart disease suffering from poor weight gain.

In view of the foregoing, the copending application claims and the current application claims are obvious variants.

Claims 17,19-47 and 49-57 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-18 and 21-36 of copending Application No. 10/748732, in view of Rice et al., Neurology

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending application teaches an infant formula comprising seven carbon fatty acids such as n-heptanoic acid and a triglyceride comprising n-heptanoic acid (n-heptanoin) in the treatment of a metabolic disorder. The present application teaches methods of use claims containing the instant composition in treating a cardiac disorder. As evident by Rice et al., a metabolic disorder comprises cardiac disorders (see pg. 4 underlined). Thus one of ordinary skill in the art would have been motivated to administer the same composition with a seven carbon chain acid (n-heptanoic acid) to a patient suffering from either a metabolic or cardiac disorder (fatty acid oxidation defects). See pg. 4 as above. Therefore, the copending claims therein are obvious variants of the claims of the instant application.

These are a provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
7/25/07

Phyllis Spivack

PHYLLIS SPIVACK
PRIMARY EXAMINER